RIN 0910-AC48; Docket No. 02N-0417

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Concerning

PATENT LISTING REQUIREMENTS AND APPLICATION OF 30-MONTH STAYS ON APPROVAL OF ABBREVIATED NEW DRUG APPLICATIONS CERTIFYING THAT A PATENT CLAIMING A DRUG IS INVALID OR WILL NOT BE INFRINGED

Daniel J. Popeo
Richard A. Samp
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

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Washington Legal Foundation
2009 Massachusetts Avenue
Washington, DC 20036
(202) 588-0302

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Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not be Infringed
Docket No. 02N-0417; 67 Fed. Reg. 65448 (Oct. 24, 2002)

The Washington Legal Foundation is filing these comments to offer its qualified support to the Food and Drug Administration's (FDA) proposed rule regarding the application of 30-month stays on approval of Abbreviated New Drug Applications (ANDA). WLF agrees with FDA (and conclusions reached by the Federal Trade Commission (FTC) in its July 2002 report entitled *Generic Drug Entry Prior to Patent Expiration: An FTC Study*) that pioneer drug companies have on occasion improperly delayed entry of generic competition by invoking existing regulations to obtain multiple 30-month stays in the granting of ANDAs. WLF also agrees with FDA that it possesses statutory authority to adopt a rule stating that the 30-month stay may be invoked only once in connection with any ANDA.

WLF nonetheless disagrees with portions of FDA's statutory analysis and believes that FDA lacks authority to adopt proposed 21 C.F.R. § 314.95(a)(3). In particular, FDA has misread Section 505(j)(2)(B)(iii) of the Federal Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 355(j)(2)(B)(iii); that section cannot not plausibly be read in the manner proposed by FDA. Moreover, it makes little sense as a policy matter to declare that only the first Paragraph IV certification filed by an

ANDA applicant can give rise to a 30-month stay. Rather, because a principal purpose of the Hatch-Waxman Act was to encourage the resolution of patent infringement disputes *before* a generic manufacturer begins marketing its product, the law ought to be interpreted as permitting a single 30-month stay, with that stay commencing on the date on which the generic manufacturer provides the required notice with regard to the Paragraph IV certification that initially triggered the pioneer manufacturer's patent infringement action. If a pioneer manufacturer decides not to file an infringement action with respect to one patent for which a Paragraph IV certification has been filed, it should not thereby forfeit its right to seek a 30-month stay with respect to later patents that are issued before the ANDA is approved.

Interests of WLF. WLF is a public interest law and policy center headquartered in Washington, D.C., with supporters in all 50 states. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery. *See, e.g., Pharmaceutical Research and Manufacturers of America v. Concannon,* 249 F.3d 66 (1st Cir. 2001), *cert. granted*, 70 U.S.L.W. 3798 (U.S. June 28, 2002) (constitutionality of Maine prescription drug price controls). WLF recently successfully challenged the constitutionality of FDA restrictions on speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd,* 202 F.3d 331 (D.C. Cir. 2000). WLF has participated in several lawsuits concerning the proper interpretation of the balance struck by the Hatch-Waxman Act between the competing interests of pioneer and generic pharmaceutical manufacturers. *See, e.g., Mylan Pharmaceuticals, Inc. v.*

Thompson, 268 F.3d 1323 (Fed. Cir. 2001); *Allergan, Inc. v. Alcon Laboratories, Inc.,* No. 02-1449 (Fed. Cir., dec. pending).

WLF believes that both pioneer and generic pharmaceutical manufacturers play an important role in our health care system. WLF believes that if advances in health care are to continue, it is vital that pioneer companies that develop new drugs and medical devices be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. That exclusivity period provides an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies will be able to reap substantial rewards in those few instances in which their research and development expenditures bear fruit. On the other hand, once an appropriate period of exclusivity has expired, consumers are well served by government policies that encourage other companies to market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

There is an inherent tension between these two goals – rewarding research and development while lowering the cost of drugs through competition. Congress attempted to strike a balance between those competing interests when, in 1984, it adopted the Hatch-Waxman Act. WLF supports the balance struck by Congress. The competing interests of pioneer and generic drug manufacturers inevitably result in litigation over precisely when a pioneer manufacturer's exclusivity period should end and when a generic manufacturer should be permitted to begin selling copycat drugs. The Hatch-Waxman Act provides detailed rules regarding how such disputes are to be resolved. As the agency charged with enforcing many provisions of the Hatch-Waxman Act, FDA's interpretation of the Act is entitled to substantial deference. Nonetheless, WLF opposes any efforts by FDA to re-write the

compromise worked out by Congress. WLF believes that any such re-writing should be done by Congress itself, not by FDA.

Statutory Framework. Congress created the ANDA procedure as part of its 1984 Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* Pub. L. 98-417, 98 Stat. 1585 (1984), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Hatch-Waxman Act is Congress's attempt to strike a balance between the competing interests of pioneer and generic drug manufacturers. The Act benefited generic manufacturers by creating the ANDA procedure, which greatly streamlined the process by which generic manufacturers can receive FDA approval to market generic copies of pioneer drugs. 21 U.S.C. § 355(j). The Act benefited pioneer manufacturers by granting patent-term extensions under certain circumstances. 35 U.S.C. § 156.

The Act also set forth procedures for resolving patent disputes between pioneer and generic manufacturers. Those procedures are set forth in § 505(j) of the FDCA, 21 U.S.C. § 355(j). The FDCA provides that FDA is to maintain a list of FDA-approved drugs and to include on that list any patent information respecting those drugs. 21 U.S.C. § 355(j)(7)(A). That FDA list is generally referred to as the "Orange Book." If a generic manufacturer seeks to market a generic version of an approved drug for which a patent is claimed in the Orange Book, the manufacturer must include in its ANDA a certification "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[1]

1 Such a certification is often referred to as a "Paragraph IV Certification."

A generic manufacturer that makes a Paragraph IV Certification must include in its ANDA a statement that it has provided notice of the Certification both to the owner of the patent that is the subject of the Certification and to the holder of the approved NDA for the drug in question. 21 U.S.C. § 355(j)(2)(B)(i) and (ii). The Act further provides that if an ANDA is amended "to include" a Paragraph IV Certification, the notice required by §§ (B)(i) and B(ii) "shall be given when the amended application is submitted." 21 U.S.C. § 355(j)(2)(B)(iii).

An ANDA that includes a Paragraph IV certification and that is otherwise proper must be approved immediately by FDA unless the patent holder files an infringement action within 45 days of the date on which the applicant notifies the patent holder that a Paragraph IV certification has been filed. 21 U.S.C. § 355(j)(5)(B)(iii). If an infringement action is filed within that 45-day period, then the FDCA provides:

> [T]he approval [of the ANDA] should be made effective upon the expiration of the thirty-month period beginning on the date of the receipt [by the patent holder of notice of the Paragraph IV Certification] or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –
>
> (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval should be made effective on the date of the court decision.

Id. The FDCA further provides that the ANDA applicant may not file a lawsuit for "a declaratory judgment with respect to the patent" until 45 days after the patent holder receives notice of the Paragraph IV Certification. *Id.*

FDA's Proposal. In its Federal Register notice, FDA expressed concern over what it viewed as abuse of § 355(j)(5)'s 30-month stay provision by pioneer drug manufacturers. FDA noted that the number of such stays per product has been increasing; while before 1998, "patent infringement litigation

generated, at most, one 30-month stay per drug product per ANDA," in recent years there have been many cases involving multiple 30-month stays for products with substantial annual sales. 67 Fed. Reg. at 65455 (quoting FTC Report). The FDA stated that in many cases, the stays were triggered by Orange Book filings that may well not have met the criteria for Orange Book filing (and thus may well have been filed solely for the purpose of triggering a 30-month stay). *Id.*

FDA's proposal concludes that the patent rights of pioneer manufacturers can be fully protected if they are granted one Paragraph IV Certification notice and one opportunity for a stay of up to 30 months (while patent infringement litigation is resolved), while at the same time eliminating potential for abuse of the 30-month stay provision. *Id.* at 65455-56. The proposal examines the language of the Hatch-Waxman Act and its legislative history and concludes that a regulation limiting pioneer drug manufacturers to a single 30-month stay is consistent with both the Act's language and its legislative history. *Id.* Accordingly, FDA proposes to amend its current regulations (which provide for a 30-month stay each time a Paragraph IV Certification triggers patent infringement litigation) to provide that the 30-month stay can be triggered on only the first occasion that a generic manufacturer files a Paragraph IV Certification.

In defense of its new interpretation of the Hatch-Waxman Act, FDA relies primarily on § 355(j)(2)(B)(iii), which provides:

> If an [ANDA] is amended to include a certification described in subparagraph (A)((vii)(IV) [*i.e.*, a Paragraph IV Certification], the notice [to the patent holder and the holder of the approved NDA] required by clause (ii) shall be given when the amended application is submitted.

FDA interprets § (2)(B)(iii) as requiring notification on only the first occasion on which an ANDA is

amended to include a Paragraph IV Certification. FDA concludes that because no notification is required for subsequently-filed Paragraph IV Certifications and because the 30-month stay provision can only be triggered by a suit filed in response to such a notification, suits filed in response to any Certification filed by a generic drug company after its initial Paragraph IV certification cannot give rise to a 30-month stay.

FDA's Interpretation of § (2)(B)(iii) Is Implausible. WLF agrees with FDA that on some occasions, pioneer manufacturers have misused the 30-month stay provision, with the result that the onset of generic competition has been delayed unnecessarily. WLF further agrees with FDA that it has a plausible basis for interpreting the Hatch-Waxman Act as limiting pioneer manufacturers to a single 30-month stay. However, WLF believes that FDA's reliance on § 355(j)(2)(B)(iii) as the primary basis for its conclusion is wholly implausible. Furthermore, the result of FDA's reliance on § (2)(B)(iii) is to hamstring pioneer manufacturers in a manner never intended by Congress. WLF respectfully suggests that FDA can adopt regulations that limit pioneer manufacturers to a single 30-month stay but in a manner that does not (as does FDA's proposal) significantly erode pioneer manufacturers' patent rights.

WLF agrees with FDA that the Hatch-Waxman Act's legislative history indicates that Congress contemplated that no more than one 30-month stay would be granted in connection with patent infringement litigation filed in response to a Paragraph IV Certification. That intent is reflected in the language of 21 U.S.C. § 355(j)(5)(B)(iii). That section states that FDA approval of an ANDA containing a Paragraph IV Certification shall be made effective immediately unless "an" action is brought for patent infringement within 45 days, in which case approval shall be effective no later than the expiration date of "the" 30-months period following receipt of "the" notice of the Certification provided

by the ANDA applicant pursuant to § 355(j)(2)((B)(i). WLF respectfully suggests that Congress's use of the singular on three occasions ("an" action, "the" period, and "the" notice) indicates that § 355(j)(5)(B)(iii) was intended to allow no more than one 30-month stay in connection with a single ANDA. Even if that is not the only permissible interpretation, it is certainly a plausible one. Congress clearly had only one patent infringement lawsuit in mind, and its reference to "the" notice that marks the commencement of "the" 30-month stay can logically be equated with the notice that initially triggered the patent infringement litigation -- even if the pioneer manufacturer receives additional § (2)(B)(i) notices after suit has been filed.

However, rather than relying on § (5)(B)(iii) for its conclusion that only a single 30-month stay is permissible, the FDA proposal seeks to rely on § (2)(B)(iii). That section requires that notice be provided to the patent holder and the holder of an approved NDA whenever an ANDA is "amended to include a" Paragraph IV Certification. FDA proposes to interpret the phrase "amended to include a" as encompassing an ANDA amendment *only* if the Certification attached to the amendment is the *first* Certification attached to the ANDA. 67 Fed. Reg. at 65455. That simply is not a plausible interpretation of the phrase. The word "include" means "to take in or comprise as a part of a larger aggregate or principle." *Webster's New Collegiate Dictionary* (G. & C. Merriam Co. 1981). Whenever an ANDA is amended to attach a Paragraph IV Certification, the new Certification has been "included" in the ANDA (*i.e.,* it is thereafter "a part of" the ANDA) regardless whether it is the first such Certification.[2] So long as a second or subsequent Certification is not identical to any prior Certification,

[2] FDA states, "[I]f the ANDA contained a paragraph IV certification, then any ANDA amendment containing a paragraph IV certification does not amend the ANDA to 'include' a paragraph

it adds to the ANDA and thus has been "include[d]" within the meaning of § 355(j)(2)(B)(iii). Whenever such a Certification is "included" in an ANDA amendment, the § 355(j)(2)(B)(i) and (ii) notification requirement is triggered.[3]

FDA's effort to rely on § 355(j)(2)(B)(iii), rather than (as WLF's proposes) relying on § 355(j)(5)(B)(iii), is of significant practical importance. Under WLF's interpretation, a pioneer manufacturer may invoke the 30-month stay only once, but it may do so in connection with the patent of its choice. Under FDA's proposal, only the patent cited in the first Paragraph IV Certification can trigger a 30-month stay, and will do so *only* if the patent holder chooses to initiate patent infringement litigation within 45 of the date of notification. Such a rule can be of considerable hardship to the pioneer manufacturer. There is no reason to force an NDA or patent holder to use its single 30-month stay to litigate narrow patents when more protective patents are likely to issue before the ANDA is approved.

IV certification because the ANDA already contained a paragraph IV certification." *Id.* That statement is nonsense. As noted above, the word "include" does not mean (as FDA suggests it means) "add an item that is the first of its kind."

[3] FDA's contrary interpretation is also inconsistent with and undermines Congress's expressed desire that patent holders be given the first crack at determining the timing and venue of patent infringement litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iii) (patent holder has the exclusive right to file patent infringement llitigation during the first 45 days following submission of a Paragraph IV Certification).

This situation is likely to arise with some frequency. For example, where an ANDA is filed during an exclusivity period (whether granted by patent or due to approval of an NDA), it may include Paragraph IV Certification(s) filed with respect to patents that the NDA holder was *required* to list in the Orange Book but that may, in fact, not cover a particular formulation of the generic drug product. Under this scenario, the NDA holder is unable to bring an infringement action in good faith, and so no 30-month stay takes effect. If a patent covering the broader formulation proposed by the generic manufacturer is later issued, the manufacturer would be required to amend its ANDA to include an additional Paragraph IV Certification, but the pioneer manufacturer would be forced (under FDA's proposal) to conduct any subsequent patent infringement litigation without the protection of the 30-month stay. Moreover, because delisting of patents is not an option for patents whose listing in the Orange Book is required by statute, FDA's proposed rule unfairly penalizes pioneer manufacturers, who have little or no control over either their Orange Book listings or the timing of patent issuance by the U.S. Patent and Trademark Office.

Finally, in establishing an elaborate set of procedural rules for resolving patent disputes between pioneer and generic manufacturers, the Hatch-Waxman Act unequivocally expressed Congress's desire for speedy and inexpensive resolution of such disputes; FDA's proposed rule would undercut that goal. To ensure speedy resolution, Congress provided that patentees have only 45 days to bring an infringement suit if they wish to challenge a generic company's Paragraph IV Certification and take advantage of the 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii). Delays in issuance of an ANDA caused by the pendency of such suits are limited to a maximum of 30 months (and can be shortened significantly by court order). *Id.* Also, Congress explicitly limited the damage awards that can be

awarded to patentee in such suits. 35 U.S.C. § 271(e)(4)(A).

Contrary to Congress's intent, FDA's proposed rule guarantees that many patent disputes will be resolved only after an ANDA has been approved and marketing of the generic drug has begun. Because FDA's proposal denies them the right to seek a 30-month stay in many instances, pioneer manufacturers will have little incentive to file suit within 45 days of their receipt of notification of the Paragraph IV Certification. Courts hearing the patent disputes will have far less incentive to expedite consideration of those disputes in comparison to other actions pending before them. Because of the huge potential damages created in any patent dispute involving the marketing of a generic version of a drug,[4] the parties will have much more difficulty arriving at an amicable settlement once generic marketing has begun. WLF submits that this scenario is the precise opposite of the one envisioned by Congress when it adopted the Hatch-Waxman Act.

[4] Generic drugs are generally sold at a small fraction of the price previously offered by a pioneer manufacturer with market exclusivity. Thus, the profits derived by a generic manufacturer from its sale of a generic alternative product will be dwarfed by the profits lost by the pioneer manufacturer. Accordingly, a damage award issued in a pharmaceutical patent infringement case would likely drive a generic manufacturer into bankruptcy, and thus most likely would never be collected by a pioneer manufacturer.

Conclusion. WLF applauds FDA for taking steps to end abuses of the 30-month stay provision by some pioneer manufacturers. However, FDA's proposed solution does not comply with the Hatch-Waxman Act and would have severe negative consequences. WLF proposes that the rule be amended to make clear that whenever a pioneer manufacturer first files a patent infringement suit in response to a Paragraph IV Certification and does so within 45 days of notification, the 30-month stay on issuance of the ANDA begins to run from the date on which the manufacturer received notice of the Certification giving rise to the initial filing of the suit.

Respectfully submitted,

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Daniel J. Popeo

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Richard A. Samp

WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302 (voice)
(202) 588-0386 (fax)
rsamp@wlf.org

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